

# CERTIFICATE OF IVD NOTIFICATION

Ref. No.: AP 1572-2021

Order No.: GR 1028- 2021 N

Belgium

Date: 01/06/2021

name: Henan Celnovte Biotechnology ,Ltd.

Address:

as stipulated and demanded by the aforementioned directive.

In-vitro diagnostic medical devices: Please See Annex A - List of Devices ( 5 pages, 50 Devices)



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### Annex A - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / EDMS	Class
1.	CAM-0201	AMACR/p504s Antibody Reagent (Immunohistochemical)	AMACR/p504s Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of AMACR/p504s antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57510	IVD Others
2.	CCM-0332	CD3 Antibody Reagent (Immunohistochemical)	CD3 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD3 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56926	IVD Others
3.	CCM-0354	CD5 Antibody Reagent (Immunohistochemical)	CD5 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD5 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56930	IVD Others
4.	CCM-0391	CD10 Antibody Reagent (Immunohistochemical)	CD10 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD10 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56938	IVD Others
5.	CCM-0461	CD20 Antibody Reagent (Immunohistochemical)	CD20 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD20 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56954	IVD Others
6.	CCM-0483	CD23 Antibody Reagent (Immunohistochemical)	CD23 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD23 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56960	IVD Others
7.	CCM-0523	CD30 Antibody Reagent (Immunohistochemical)	CD30 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD30 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56968	IVD Others
8.	CCM-0550	CD34 Antibody Reagent (Immunohistochemical)	CD34 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD34 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56974	IVD Others

9.	CCM-0572	CD38 Antibody Reagent (Immunohistochemical)	CD38 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD38 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56978	IVD Others
10.	CCM-0621	CD45 Antibody Reagent (Immunohistochemical)	CD45 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD45 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56988	IVD Others
11.	CCM-0662	CD56 Antibody Reagent (Immunohistochemical)	CD56 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD56 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56998	IVD Others
12.	CCM-0701	CD68 Antibody Reagent (Immunohistochemical)	CD68 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD68 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57010	IVD Others
13.	CCM-0734	CD79a Antibody Reagent (Immunohistochemical)	CD79a Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD79a antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57018	IVD Others
14.	CCM-0802	CD163 Antibody Reagent (Immunohistochemical)	CD163 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of CD163 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	62796	IVD Others
15.	CCM-0852	Chromogranin Antibody Reagent (Immunohistochemical)	Chromogranin Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of Chromogranin antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57052	IVD Others
16.	CEM-0081	Estrogen Receptor Antibody Reagent (Immunohistochemical)	Estrogen Receptor Antibody Reagent (Immunohistochemical)	This reagent was used for in vitro semi-quantitative detection of estrogen receptor in 10% neutral buffered formalin fixed paraffin-embedded tissue section cells.	57210	IVD Others
17.	CDM-0023	Desmin Antibody Reagent (Immunohistochemical)	Desmin Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of Desmin antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57174	IVD Others
18.	CDM-0033	DOG1 Antibody Reagent (Immunohistochemical)	DOG1 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of DOG1 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	62797	IVD Others
19.	CEM-0021	E-Cadherin Antibody Reagent (Immunohistochemical)	E-Cadherin Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of E-Cadherin antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	56863	IVD Others

20.	CER-0032	EGFR (Epidermal growth factor receptor Antibody Reagent (Immunohistochemical))	EGFR (Epidermal growth factor receptor Antibody Reagent (Immunohistochemical))	This reagent was used for the qualitative determination of EGFR (Epidermal growth factor receptor) antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57184	IVD Others
21.	CCM-0844	HER2 Antibody Reagent (Immunohistochemical)	HER2 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of HER2 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue section cells.	57047	IVD Others
22.	CMM-0202	MSH6 Antibody Reagent (Immunohistochemical)	MSH6 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of MSH6 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57433	IVD Others
23.	CNM-0012	Napsin A Antibody Reagent (Immunohistochemical)	Napsin A Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of Napsin A antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	62811	IVD Others
24.	CNM-0082	NSE Antibody Reagent (Immunohistochemical)	NSE Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of NSE antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57486	IVD Others
25.	CPM-0103	p16 Antibody Reagent (Immunohistochemical)	p16 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of p16 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57495	IVD Others
26.	CPM-0133	p40 Antibody Reagent (Immunohistochemical)	p40 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of p40 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	64957	IVD Others
27.	CPM-0160	p63 Antibody Reagent (Immunohistochemical)	p63 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of p63 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57517	IVD Others
28.	CPM-0404	PSA Antibody Reagent (Immunohistochemical)	PSA Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of PSA antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	63066	IVD Others
29.	CPM-0140	p53 Antibody Reagent (Immunohistochemical)	p53 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of p53 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57515	IVD Others
30.	CAM-0191	SMA Antibody Reagent (Immunohistochemical)	SMA Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of SMA antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57581	IVD Others

31.	CSM-0250	Synaptophysin Antibody Reagent (Immunohistochemical)	Synaptophysin Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of synaptophysin antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections	57626	IVD Others
32.	CSM-0101	S100 Antibody Reagent (Immunohistochemical)	S100 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of S100 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections	60649	IVD Others
33.	CTM-0263	Thyroid Transcription Factor-1 (TTF-1) Antibody Reagent (Immunohistochemical)	Thyroid Transcription Factor-1 (TTF-1) Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of thyroid transcription factor-1 (TTF-1) antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57665	IVD Others
34.	CTM-0150	Thyroglobulin Antibody Reagent (Immunohistochemical)	Thyroglobulin Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of thyroglobulin antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections	57656	IVD Others
35.	CTM-0233	TOP2A Antibody Reagent (Immunohistochemical)	TOP2A Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of TOP2A antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57670	IVD Others
36.	CVM-0031	Villin Antibody Reagent (Immunohistochemical)	Villin Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of villin antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57700	IVD Others
37.	CCM-0983	Cytokeratin 5&6 Antibody Reagent (Immunohistochemical)	Cytokeratin 5&6 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of cytokeratin 5&6 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57079	IVD Others
38.	CCM-0992	Cytokeratin 7 Antibody Reagent (Immunohistochemical)	Cytokeratin 7 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of cytokeratin 7 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57079	IVD Others
39.	CCM-1102	Cytokeratin 19 Antibody Reagent (Immunohistochemical)	Cytokeratin 19 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of cytokeratin 19 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57079	IVD Others
40.	CCM-1113	Cytokeratin 20 Antibody Reagent (Immunohistochemical)	Cytokeratin 20 Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of cytokeratin 20 antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57079	IVD Others
41.	CCM-0960	Cytokeratin (Broad spectrum) Antibody Reagent (Immunohistochemical)	Cytokeratin (Broad spectrum) Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of broad spectrum cytokeratin antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57079	IVD Others

42.	CCM-0900	Cytokeratin (high molecular weight) antibody reagent (immunohistochemistry)	Cytokeratin (high molecular weight) antibody reagent (immunohistochemistry)	This reagent was used for the qualitative determination of High molecular weight cytokeratin antigen in 10% neutral buffered formalin fixed paraffin embedded tissue sections.	57079	IVD Others
43.	CPM-0365	Progesterone Receptor Antibody Reagent (Immunohistochemical)	Progesterone Receptor Antibody Reagent (Immunohistochemical)	This reagent was used for the qualitative determination of progesterone receptor antigen in 10% neutral buffered formalin fixed paraffin-embedded tissue sections.	57210	IVD Others
44.	CF1299	FISH detection Kit for the apart of BCL2(18q21) gene	FISH detection Kit for the apart of BCL2(18q21) gene	This kit is used for in situ hybridization staining based on routine staining to provide auxiliary information for physicians in diagnosis.	56826	IVD Others
45.	CF1297	FISH detection Kit for the apart of BCL6 gene	FISH detection Kit for the apart of BCL6 gene	This kit is used to qualitatively detect the diagnosis of BCL6 gene rearrangement in lymphoma. To guide the treatment and prognosis evaluation of lymphoma, not for disease screening or diagnosis	56827	IVD Others
46.	CF1256	FISH detection Kit for the apart of C-MYC gene	FISH detection Kit for the apart of C-MYC gene	This kit is used to qualitatively detect the diagnosis of C-MYC gene rearrangement in lymphoma. To guide the treatment and prognosis evaluation of lymphoma, not for disease screening or diagnosis	60208	IVD Others
47.	CF1326	Chromosome and gene abnormality detection kit for myelodysplastic syndromes (In Situ Hybridization)	Chromosome and gene abnormality detection kit for myelodysplastic syndromes (In Situ Hybridization)	This kit is used for in situ hybridization staining based on routine staining to provide auxiliary information for physicians in diagnosis.	61681	IVD Others
48.	CF1240	BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit	BCR/ABL Dual Color, Dual Fusion Translocation Probe Kit	This kit is used to qualitatively detect BCR/ABL gene fusion in patients with hematological tumors.	47962	IVD Others
49.	CF1121	PML/RARA Dual Color, Dual Fusion Translocation Probe Kit	PML/RARA Dual Color, Dual Fusion Translocation Probe Kit	This kit is used to qualitatively detect PML/RARA gene fusion in patients with acute myeloid leukemia (AML).	60077	IVD Others
50.	SD5100	MicroStacker™ Polymer Staining Kit	MicroStacker™ Polymer Staining Kit	In the immunohistochemical reaction or in situ hybridization reaction, the target is bound to the primary antigen antibody and labeled by staining.	44663	IVD Others

\* Annex A is part of the Agreement.

\*\* The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

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